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K061424

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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Celsite®/Celsite® Concept™ Access Ports
May 3, 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: Celsite®/Celsite® Concept™ Access Ports

COMMON NAME: Port & Catheter, Implanted, Subcutaneous, Intravascular

CLASSIFICATION NAME: Port & Catheter, Implanted, Subcutaneous, Intravascular

REGULATION NUMBER: 880.5965

PRODUCT CODE: LJT

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Celsite®/ Celsite® Concept™ Access Ports are substantially equivalent to Aesculap's currently marketed Celsite® Access Port Systems (K902401, K952548, K954297, K962230, K993024) and Deltec Inc., PORT-A-CATH® II (K032557, K992697, K932840).

DEVICE DESCRIPTION

The Celsite®/ Celsite® Concept™ Access Ports are an implantable port and catheter system which allows safe, repeated access to the patient's bloodstream. The port chamber and catheter design can be used for the administration of medications and fluids.

INDICATIONS FOR USE

The Aesculap Celsite®/Celsite® Concept™ Access Ports are indicated for intra-venous administration of drugs for chemotherapy, antibiotics and anti-viral drugs, and for parenteral nutrition, blood sampling or transfusions.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Celsite®/ Celsite® Concept™ Access Ports is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing results of the subject device showed to be similar in performance to the previously cleared Aesculap® Access Ports with similar indications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

Ms. Lisa Boyle
Regulatory Affairs Specialist
Aesculap[®], Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K061424
Trade/Device Name: Celsite[®]/Celsite[®] Concept[™] Access Ports
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 22, 2006
Received: May23, 2006

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

